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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,513	01/24/2002	Kurt C. Gish	018501-005910US	5387

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,513	GISH ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed November 15, 2002 is acknowledged and has been entered.

2. Claims 1-39 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1 and 2, drawn to a method for screening drug candidates comprising determining the effect of a drug candidate upon the expression of a gene encoding PBH1 in a cell, classified in class 435, subclass 6.

Group II. Claim 3, drawn to a method for screening bioactive agents capable of binding to PBH1 or a fragment thereof comprising determining if a candidate bioactive agent can bind PBH1 or a fragment thereof, classified in class 435, subclass 7.1.

Group III. Claim 4, drawn to a method for screening bioactive agents capable of modulating the activity of PBH1 comprising determining the effect of a candidate bioactive agent upon the activity of PBH1, which cannot be classified because the activity of PBH1 is not specified.

Group IV. Claims 5 and 6, drawn to a method for evaluating the effect of a candidate drug comprising administering a candidate drug to a patient and determining the effect of the drug upon expression of a gene encoding PBH1 or a fragment thereof, classified in class 435, subclass 6.

Group V. Claim 7, drawn to a method for diagnosing prostate cancer comprising determining the expression levels of a gene encoding PBH1 in an individual and an unaffected individual and comparing the expression levels, classified in class 435, subclass 6.

Group VI. Claims 8-13, drawn to an antibody that binds specifically to PBH1 or a fragment thereof, classified in class 530, subclass 387.1+.

Group VII. Claims 14 and 15, drawn to a method for screening bioactive agents capable of interfering with the binding of PBH1 or a fragment thereof and an antibody that binds specifically to PBH1 or a fragment thereof, classified in class 435, subclass 7.1.

Group VIII. Claims 16-18, drawn to a method for inhibiting the activity of, or neutralizing PBH1 comprising binding an inhibitor to PBH1, which cannot be classified because the activity of PBH1 is not specified.

Group IX. Claims 19-26, drawn to a method for treating prostate cancer or localizing a therapeutic moiety to prostate cancer comprising administering to a patient an inhibitor of PBH1, classified, for example, in class 424, subclass 155.1.

Group X. Claim 27, drawn to a method for inhibiting prostate cancer in a cell comprising administering to the cell an antisense molecule, classified in class 514, subclass 44.

Group XI. Claim 28, drawn to a biochip, classified in class 422, subclass 82.08.

Group XII. Claim 29, drawn to a method for eliciting an immune response comprising administering to an individual a composition comprising PBH1 or a fragment thereof, classified in class 424, subclass 277.1.

Group XIII. Claim 30, drawn to a method for eliciting an immune response comprising administering to an individual a composition comprising a nucleic acid encoding PBH1 or a fragment thereof, classified in class 514, subclass 44.

Group XIV. Claim 31, drawn to a method for determining the prognosis of an individual with prostate cancer comprising determining the level of PBH1 is a sample, classified, for example, in class 435, subclass 7.21.

Group XV. Claims 32-37, drawn to a polypeptide, classified in class 530, subclass 350.

Group XVI. Claims 38 and 39, drawn to a nucleic acid molecule encoding a protein, classified in class 536, subclass 23.5.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups VI, XI, XV, and XVI are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct. As further evidence the inventions of groups VI, XI, XV, and XVI are distinct, the search that would be required to consider each would not the same or co-extensive with the search required to consider any other.

The inventions in groups I-V, VII-X, and XII-XIV are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct. For example, the

inventions of groups I-III most notably differ from one another in that each comprises a different assay measuring a different effects or substances; and the inventions of groups I-III differ from the inventions of groups IV, V, VII-X, and XII-XIV in objective and process. Other inventions, such as the inventions of groups XII and XIII are materially different processes comprising administering chemically distinct substances and have different criteria for success. As further evidence the inventions of groups I-V, VII-X, and XII-XIV are distinct, the search that would be required to consider each would not the same or co-extensive with the search required to consider any other.

Inventions in group VI and inventions in groups VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the antibody can be used in a materially different process of using that product, such as the process of purifying the protein to which the antibody binds by affinity chromatography.

Inventions in group XV and inventions in groups II, III, and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the protein can be used in a materially different process of using that product, such as the process of purifying an antibody, which binds the protein by affinity chromatography.

Inventions in group XVI and inventions in groups XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the nucleic acid molecule can be used in a

materially different process of using that product, such as the process of using the nucleic acid molecule as a probe to detect the nucleic acid in a sample.

The inventions in group VI and groups I-V, X, and XII-XIV are not at all related because the products of group VI are not specifically used in any of the steps of the claimed methods in groups I-V, X, and XII-XIV.

The inventions in group XI and groups I-V, VII-X, and XII-XIV are not at all related because the products of group XI are not specifically used in any of the steps of the claimed methods in groups I-V, VII-X, and XII-XIV.

The inventions in group XV and groups I, IV, V, VII-X, XIII, and XIV are not at all related because the products of group XV are not specifically used in any of the steps of the claimed methods in groups I, IV, V, VII-X, XIII, and XIV.

The inventions in group XVI and groups I-V, VII-X, XII, and XIV are not at all related because the products of group XVI are not specifically used in any of the steps of the claimed methods in groups I-V, VII-X, XII, and XIV.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or**

otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 23, 2004

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SUPERVISORY PATENT EXAMINER
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